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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,836	06/01/2001	Shikha P. Barman	08191-018001	3677

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BOSTON, MA 02110

EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,836

Applicant(s)

BARMAN ET AL.

Examiner

Dave T. Nguyen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-16, 21-29, 31-34, drawn to a polymeric composition comprising a polymer matrix, a lipid having a pKa of less than about 2.5 and DNA, wherein the polymeric microparticle is less than about 100 microns, and method of using the polymeric composition to deliver an encoded DNA molecule to a subject, classified in class 435, subclass 320.1, and Class 514, subclass 44.

Group I. Claims 17-20, drawn to a polymeric composition comprising a polymer matrix, a zwitterionic lipid and a DNA, wherein the polymeric microparticle is less than about 100 microns, and method of using the polymeric composition to deliver an encoded DNA molecule to a subject, classified in class 435, subclass 320.1, and Class 514, subclass 44.

Group III. Claims 35-36, drawn to a method of preparing an aqueous solution of DNA in a polymeric composition, wherein the steps of mixing solutions to produce a first emulsion, second emulsion, and third emulsion, wherein the shearing of the DNA is minimized, and wherein microparticles having an average diameter smaller than 100 microns, classified in class 435, subclass 320.1, class 424, subclass 468, and class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Group I and Group I are distinct because each of the groups is directed to a distinct lipid employed in the claimed polymeric microparticle. One has to do with a lipid

having a pKa of less than about 2.5, and the other has to do with a zwitterionic lipid. Given that the lipid as claimed is a major constituent of the claimed composition, a search and examination of both Groups would constitute a undue burden to the examiner.

Group III and Group I are related as process of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, an aqueous solution containing a DNA of invention I can be encapsulated by a polymeric microparticle of Invention I by using conventional techniques such as interfacial microencapsulation, solvent extraction, and physical encapsulation. Thus, the polymeric compositions cited in Group I can be made by processes other than the process cited in Group III.

Should Group I be elected, the claims are generic to a plurality of disclosed patentably distinct species comprising:

- A/ a DNA encoding a naturally-occurring mammalian polypeptide;
- B/ a DNA encoding a peptide which binds to an MHC class I molecule;
- C/ a DNA encoding a peptide which binds to an MHC class II molecule;
- D/ a DNA encoding a naturally occurring protein from an infectious agent;

Should species A, B, C, or D be elected, item (d) will only be searched and examined to the extent that item (d) is encompassed by the elected species.

Should Group I be elected, Applicant is required under 35 U.S.C. 121 to elect a

Art Unit: 1632

single disclosed species as listed above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Group I, and the species of A, B, C, or D be elected, claims 2-5 are generic to a plurality of disclosed patentably distinct species comprising each of the species as listed in claims 2 and subsequently in claim 3

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the lipid cited in claim 9, even though this requirement is traversed.

Should Group II be elected, claim 18 is generic to a plurality of disclosed patentably distinct species comprising each of the species as listed in the claim.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the lipid cited in claim 9, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

Art Unit: 1632

the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Application/Control Number: 09/872,836
Art Unit: 1632

Page 6

Dave Nguyen
Primary Examiner
Art Unit: 1632

A handwritten signature in black ink, appearing to read 'Dave', with a long, sweeping horizontal line extending to the right.

DAVE T. NGUYEN
PRIMARY EXAMINER